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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,893	02/12/2004	John Rush	CST-201 CIP	6794

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EXAMINER	
DO, PENSEE T	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/777,893	RUSH ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *40-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39 and 49-52* is/are rejected.

7)☒ Claim(s) *53* is/are objected to.

8)☒ Claim(s) *1-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 8/28/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry & Claims Status

The amendment filed on August 24, 2006 has been acknowledged and entered.

Claims 1-53 are pending.

Claims 40-48 are withdrawn from further consideration.

Claims 1-39, 49-53 are being examined.

Withdrawn Rejection(s)

Rejection under 112, 1st paragraph in the previous office action is withdrawn.

Maintained Rejection(s)

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-29 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-29 of copending Application No. 10/777,893. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 13-16, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Kanner et al. (Journal of Immunological Methods, 120 (1989) 115-124).

Kanner teaches a large scale immunoaffnity purification method for isolating several populations of naturally-occurring post-translationally modified peptides (tyrosine phosphoproteins) from a complex mixture of peptides, said method comprising:

a. obtaining a proteinaceous preparation from an organism (chicken embryo cells), wherein said proteinaceous preparation comprises naturally-occurring post-translationally modified peptides from two or more different proteins (see pg 116, col. 1, paragraph 1; col. 2, materials and methods);

b. contacting the proteinaceous preparation with at least one immobilized post-translational modification specific antibody (Tyrosine phosphoproteins were purified from cells by immunoaffinity chromatography with antibodies to phosphotyrosine. (see abstract)). Since tyrosine phosphoproteins were purified from cells by immunoaffinity chromatography with antibodies to phosphotyrosine, it is inherent that the antibodies are immobilized on the chromatographic gel.

c. isolating at least one population of post-translationally modified peptides.

Claims 1, 2, 4, 5, 10, 13-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Wirth et al. (Electrophoresis 1993, 14, 1199-1215).

Wirth teaches a method for isolating a population of naturally-occurring post-translationally modified peptides from a complex mixture of peptides comprising: a). obtaining a proteinaceous preparation comprising two or more different proteins (nuclear cytosolic proteins and membrane and matrix proteins) (see 1200, col. 1); b). contacting said preparation with at least one immobilized post-translational modification specific antibody (2-D immunoblotting using antiphosphotyrosine antibodies – see 1202, 3.1.1. col. 2; 1212, col.1); c). isolating at least one population of peptides; d). further characterizing the population of modified peptides by using a search database analysis to obtain polypeptide identification number, protein name, molecular weight (mass spectrometry) and pI information. (see abstract); It is inherent that the peptides were isolated by using mass spectrometry in order to obtain molecular weight of the peptides to be compared with the database.

With respect to claim 5, Wirth teaches that the preparation can comprise whole tissue samples (crude cell extract) (see pg. 1199, col. 2, paragraph 2) or a cell extract partially purified by separation of purified cell nuclei into nuclear cytosolic and particulate fractions (digested crude cell extract) (see pg. 1200, col. 1, paragraph 1).

With respect to claim 10, the modified specific antibodies are immobilized on 2-D PAGE gel. (chromatography resin). (see page 1199, col. 2, paragraph 2).

With respect to claims 13 and 14, the modification comprises phosphorylation and the peptides are phosphopeptides. (see pg 1200, col. 1).

With respect to claim 15, Wirth teaches the use of antibodies specific to particular proteins or motifs of both phosphorylated and unphosphorylated forms, used at various points in the method (see pg. 1202, col.2 , paragraph 1; page 1212, col. 1, paragraph 1; and Fig. 6).

With respect to claim 16, Wirth teaches using a plurality of antiphosphotyrosine antibodies to recognize a plurality of phosphotyrosine motifs, wherein the search is for reported proteins having the antiphosphotyrosine motifs. (see pg. 1212, col.1 , paragraph 1; table I; and Fig. 6).

With respect to claim 17, Wirth explains that phosphoproteins are phosphorylated at the phosphotyrosine motif (a kinase consensus substrate motif) by the action of protein kinases (see 1200, col. 1, paragraph 1, last sentence).

With respect to claim 18, Wirth teaches the above methods are for identification of numerous phosphotyrosine-containing proteins prepared from their either whole cell or isolated nuclei extracts (pg. 1200, col.1, paragraph 1), thereby encompassing the kinase consensus substrates of Applicant's instant claim 14. Furthermore, Wirth specifically teaches that the kinase substrate motifs include that of the protein Vimentin (a CDK consensus substrate motif), (see table 1, pg. 1206, 1st entry) and protein Tropomyosin (a PKA consensus substrate motif) (see table 1, pg. 1207).

With respect to claim 19, Wirth implicitly teaches a monoclonal or polyclonal antibody because Wirth does not specify that the specific antibody is a fragment.

With respect to claim 20, Wirth teaches that the preparation is obtained from cancer, tumor and neoplastic transformation tissue samples (marker of disease). (see pg. 1200, col. 1, paragraph 1).

With respect to claim 21, Wirth teaches identifying an unknown post-translational modification site of said parent protein by explaining that the database can provide protein name, polypeptide identification number as well as information regarding transformation – (translational characteristics) and growth related characteristics.

With respect to claims 22 and 23, Wirth discusses that the 2-D polyacrylamide gel electrophoresis (2-D PAGE) provides detailed analysis of nuclear associated polypeptides from both normal and transformed cell lines and whole tissue samples in attempts to characterize proliferation and transformation-associated nuclear proteins as well as certain tumor specific or tumor associated proteins. (see pg. 1199, col.2, paragraph 2). Thus, it is inherent that a normal sample and a diseased sample are analyzed using 2-D PAGE.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 6-9, 11, 24-28, 30-39, 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wirth in view of Little (US 6,322,970).

Wirth has been described above.

However, Wirth fails to teach that the mass spectrometry comprises MALDI-TOF MS; the digested preparation is obtained using at least one proteolytic enzyme or chemical cleavage; said enzyme is immobilized; said enzyme is soluble and wherein the digested preparation is treated with a proteolysis inhibitor prior to step b; the proteinaceous preparation is immobilized by metal affinity chromatography (IMAC); the protein preparation is obtained from a tissue biopsy cell or a clinical fluid sample and said reference sample corresponds to a diseased organism, whereby the comparison of the protein activation provides information useful for the diagnostic of the disease; the protein preparation corresponds with an organism or treated with at least one test compound and said reference sample corresponds with an untreated organism, whereby the comparison of protein activation provides information on activation changes resulting from treatment with said test compound; the comparison identifies one modified peptide as corresponding to a parent protein not previously reported as so modified in said disease; the test compound is a cancer therapeutic. Wirth also fails to teach that the chromatography resin is contained within a column. Wirth also fails to teach a step of fractionating phosphopeptides in said protein preparation by reversed-phased chromatography to produce a fractionated proteinaceous preparation. Wirth also fails to teach quantification of isolated phosphopeptides. Wirth also fails to teach quantifying the isolated peptides by using stable isotope labeling by amino acids in cell culture (SILAC) and/or absolute quantification of peptides (AQUA) techniques.

Little teaches a method for isolating a modified peptide from a complex mixture of peptides; said method comprising the steps of :

a) obtaining a proteinaceous preparation from an organism wherein the proteinaceous preparation comprises the peptides from two or more different proteins;

b) contacting said proteinaceous preparation with at least one immobilized modification-specific antibody; and (see col. 21, lines 25-27).

c) isolating at least one modified-peptide specifically bound to said immobilized modification specific antibody in step (b)

A target polypeptide is isolated prior to being detected by mass spectrometric analysis (equivalent to claim 2 of the present invention). For examples, the target polypeptide can isolated from a cell or tissue obtained from a subject such as a human. The target polypeptide can be isolated using a reagent that interacts specifically with the target polypeptide, for example, an antibody that interacts specifically with the target polypeptide, or the target polypeptide can be fused to a tag peptide and isolated using an antibody that interacts specifically with the tag peptide. The target polypeptide can be immobilized to a solid support such as a bead or a microchip which can be a flat surface. (see col. 4, lines 24-45). The polypeptide means at least two amino acids, or amino acid derivatives, including mass modified amino acids, that are linked by a peptide bond, which can be a modified peptide bond. The polypeptide can be chemically synthesized and can be modified by chemical or enzymatic methods following translation or chemical synthesis (see col. 9, lines 30-45). The proteinaceous preparation from an organism is equivalent to a biological sample obtained from a living source, an animal, a plant, or solid material such as a tissue, cells, a cell extract, or biological fluid such as urine, blood, saliva, amniotic fluid etc. (see col. 9, lines 21-30).

The target polypeptide can be isolated by affinity purification using an antibody, avidin or other specific reagent covalently linked to a solid support. In such a method, the translation reaction is poured over the support, and the polypeptide is bound due to its specificity interacting with the reagent. Regarding claims 9, Little teaches that target polypeptide fused to a tag peptide can be isolated on a column or bed of chelated zinc or copper ions. Beds or columns having such divalent metal ions chelated thereto can be obtained from commercial source or prepared by using methods known in the art. (see col. 21, lines 25-39). Regarding claim 3, Little teaches that the mass spectrometry comprises MALDI-TOF (see col. 54, lines 46-60; col. 55, lines 29-35). The molecular mass of the a target polypeptide is determined by mass spectrometry and is compared to a standard, whereby the identity of the polypeptide can be ascertained. (see col. 3, lines 15-20). Little teaches that "determining the identity of a target polypeptide" refers to determining at least one characteristic of the polypeptide, for example, a molecular mass or charge, or the identity of at least one amino acid, or identifying a particular pattern of peptide fragments of the target polypeptide and comparing such characteristic with a polypeptide in a reference sample. (see col. 9, lines 45-55; col. 10, lines 16-55). The proteinaceous preparation corresponds to a diseased organism and the reference sample corresponds to a normal organism (see example 1). The disease is cancer. Little also inherently teaches claim 28 since Little teaches that the disease being studied is cancer and the patient is being treated has cancer. Thus, the treatment must be therapeutic. Little also teaches the protein preparation is being digested using trypsin which is a proteolytic enzyme (col. 14, line 43-60). Little has been discussed above for

teaching a method of purifying peptides from a mixture using column chromatography such as using c18 column. Column chromatography encompasses reversed-phased chromatography. Little also teaches that peptides can be purified by method such as chromatography or electrophoresis. (col. 19, lines 30-42). Little teaches quantification of peptides. (see col. 9, lines 58-64). Little teaches that the peptides can be removed by linking to a solid support (fractionation) such as c18 coated pin. (see col. 47, lines 43-45; table 1, col. 48, line 64).

Since both references teaches a method of isolating modified peptides from a complex mixture, it would have been obvious to one of ordinary skills in the art to:

- use the mass spectrometry comprising of MALDI-TOF MS as taught by Little in the method of Wirth because both references teaches characterizing the modified peptides using mass spectrometry;
- obtain the digested preparation using at least one immobilized proteolytic enzyme or chemical cleavage as taught by Little in the method of Wirth because digesting proteins by enzyme aids the proliferation of the peptides so that these peptides can be easily bound to the specific antibody described in Wirth;
- use soluble enzyme and treating the digested preparation a proteolysis inhibitor prior to step (b) as taught by Little in the method of Wirth because such digestion step aids in the proliferation or exposure of the peptides in the protein preparation to the specific antibodies that bind to

those peptides which accelerates the isolation of the peptides from the protein preparation;

- immobilize the proteinaceous preparation by metal affinity chromatography (IMAC) as taught by Little in the method of Wirth because metal ions bind to the peptides from the protein preparation through electrostatic interaction;
- obtain the protein preparation from a tissue biopsy cell or a clinical fluid sample and use a reference sample that corresponds to a diseased organism, whereby the comparison of the protein activation provides information useful for the diagnostic of the disease; use the protein preparation that corresponds with an organism or treated with at least one test compound and a reference sample that corresponds with an untreated organism, whereby the comparison of protein activation provides information on activation changes resulting from treatment with said test compound; correspond the comparison that identifies one modified peptide to a parent protein not previously reported as so modified in said disease; use a test compound is a cancer therapeutic as taught by Little in the method of Wirth since both references teach comparing results of the peptide characteristics from a control sample and testing sample. Comparison between these samples aids in the diagnostic of a disease.

- Using a chromatography resin contained within a column as taught by Little in the method of Wirth since Wirth teaches using Gel chromatography, such gel can be contained within a column so that such column can retain either the target or the non-target during elution. Thus, separation can be handled sufficiently.

It would also have been obvious to one of ordinary skills in the art to use reversed-phased column chromatography such as c18 or gel electrophoresis as taught by Little to purify peptides or fractionate protein preparations of Wirth so that the peptides are exposed to the anti-phoshorylation antibodies so that the peptides can be characterized and quantified. Regarding claims 39 and 52, since Little teaches quantification of the isolated peptides and comparing the sample with a reference sample which is the AQUA technique. Thus, one of ordinary skills in the art would have motivated to use such method because in the method of Wirth, the test sample is compared against a reference sample when using a search program to characterize the peptides and Little teaches comparing the sample against a reference sample as well. It would be convenient for one skilled in the art to use the AQUA technique to quantify the peptides since characterization of peptides requires comparing them to a reference too.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wirth in view of Little as applied to claim 11 above, and further in view of Pidgeon et al. (US 6,579,720).

Wirth and Little have been discussed above.

However, Wirth and Little fail to teach that the column being coupled to a mass spectrometer.

Pidgeon teaches a method of analyzing a compound using High Performance Liquid Chromatography (HPLC) coupled with a mass spectrometer to produce at least two sets of eluent fractions. (see col. 6, line 65-col. 7, line 41).

Since Wirth and Little teach that the target polypeptide can be isolated on a chromatography column and using mass spectrometry to analyze the polypeptide, it would have been obvious to one of ordinary skills in the art to use the HPLC column coupled to a mass spectrometer taught by Pidgeon in the method of Little because with the mass spectrometer coupled to the column, the eluents or the polypeptides can be readily analyzed without being transported to the mass spectrometer if the column were not coupled to the mass spectrometer. Thus, analysis or the spectral profiles of the targets can be quickly and conveniently obtained.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wirth in view of Little as applied to claim 25 above, and further in view of Stoughton et al. (US 5,965,352).

Wirth and Little have been discussed above.

However, Wirth and Little fail to teach the test compound comprises a kinase inhibitor.

Stoughton teaches a method for identifying pathways for drug action comprising using 2D-PAGE to perform whole genome monitoring of proteins, wherein the method

can be used to screen drugs that are protein kinase inhibitors by treating cell lines (see col. 35, lines 50-66; col. 51, lines 27-45).

It would have been obvious to one of ordinary skills in the art to combine the teachings of Stoughton with the methods of Wirth and Little and use protein kinase inhibitors, since Stoughton teaches that tyrosine kinase inhibitors are of interest as potential immunosuppressive drugs. (see Stoughton col. 35, lines 50-56).

Allowable Subject Matter

Claim 53 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed August 24, 2006 have been fully considered but they are not persuasive.

Regarding Kanner and Wirth, Applicants argue that both references fail to teach every element of the claimed subject which is drawn to a method of isolating a population of post-translationally modified peptides from a complex mixture of peptides. Rather these references teach a method of isolating proteins using anti-phosphorylated antibodies. Applicants also argue that the present invention pertains to the ***selective*** isolation of peptides not proteins.

Applicant's invention is drawn to a method comprising obtaining a ***proteinaceous preparation comprising a complex mixture of peptides***; contacting said preparation with one immobilized post-translational modification-specific antibody;

and isolating at least one population of naturally occurring post-translationally modified peptides specifically bound by said immobilized modification-specific antibody. Kanner and Wirth also teaches a step of obtaining a proteinaceous preparation. Since the proteinaceous preparation of Kanner and Wirth is the same as that of the present invention, cell lysate and that the proteinaceous preparation of the present invention comprises of a complex mixture of peptides, it is inherent that there is a complex mixture of peptides present in the proteinaceous preparation of the Kanner and Wirth. While Applicants argue that their invention isolates solely peptides, the claims contradictorily recites that the proteinaceous preparation ***comprises*** a complex mixture of peptides. The open "comprising" language has other molecules, such as proteins, other than peptides. Furthermore, Kanner and Wirth uses the same antibody as that in the present invention to contact the proteinaceous preparation/sample cell lysate, and since the antibody in the present invention can bind to peptides, then the antibody in Wirth and Kanner are also able to bind to peptides possibly present in the proteinaceous preparation in the same manner as that of the present invention.

In addition, Applicants also argue that the method of the present invention pertains to selectively isolating one population of peptides. (see arguments filed 8/24/06, pg. 9, 3rd paragraph; pg. 24, 5th paragraph). However, claim 1 recites in step C that "isolating at least one population of ...peptides". The argument is not commensurate with the scope of the invention. The language of "isolating at least one population" means that there is more than one population of peptides while "selectively

isolating one population of peptides" means that there is only one population being isolated.

In conclusion, Applicants' arguments are not commensurate with the claim language or the scope of the invention.

Regarding 103 rejections, Applicants use the same arguments for the primary references, Wirth and Kanner. Thus, no further discussion is necessary.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pensee T. Do
Patent Examiner
November 9, 2006

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